Message

From: Miller, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FA0582F5BA6540C687844F9289A4F74F-DAVID J. MILLER]

Sent: 10/31/2019 3:40:43 PM

To: Wibke Meyer [wibke.meyer@croplife.org]

Subject: RE: Epidemiology in Regulatory

Yes, it looks like our emails crossed.

Let me look at your questions.

David

From: Wibke Meyer <wibke.meyer@croplife.org>
Sent: Thursday, October 31, 2019 11:32 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: Epidemiology in Regulatory

Dear David,

Thanks so much for all the information – this will keep me busy!

I just sent you some questions to start the conversation. Let me know if you have questions on those.

Kind regards, Wibke

From: Miller, David < Miller. David @epa.gov>

Sent: 31 October 2019 16:25

To: Wibke Meyer <<u>wibke.meyer@croplife.org</u>> **Subject:** RE: Epidemiology in Regulatory

Dear Wibke,

Per my Item #1 in my original response to you below, here is some information and background material you may find useful to review ahead of any discussion.

I indicated that it might be helpful for you to see the epi/incident documents that we have produced over the last FY, with the ones that included epi (because there was at least AHS available) marked below in bold. These are the ones we have put out over the last year and this will give you an idea of the scope of things we do. Note that not all of them are in the docket yet (we are working on getting them there) but I have provided links to the ones that are.

Tier I Updates Finalized:

- 1. Phostebupirim: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 2. Flumethrin: Tier I Update Review of Human Incidents and Epidemiology for Proposed Interim Decision
- 3. Metolachlor and S-Metolachlor: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 4. Pyridalyl: Tier I (Scoping) Review of Human Incidents and Epidemiology
- 5. p-dichlorobenzene (PDCB): Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 6. Triallate: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 7. Boscalid: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 8. Saflufenacil: Revised Tier I (Scoping) Review of Human Incidents and Epidemiology

- 9. Pyrimethanil: Revised Tier I (Scoping) Review of Human Incidents and Epidemiology
- 10. Iprodione: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 11. Mesotrione: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 12. Spirotetramat: Tier I (Scoping) Review of Human Incidents and Epidemiology
- 13. Spiromesifen: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 14. Acequinocyl: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 15. Propargite: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 16. Terbacil: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 17. Pyroxsulam: Tier I (Scoping) Review of Human Incidents and Epidemiology
- 18. Thiencarbazone-methyl: Tier I (Scoping) Review of Human Incidents and Epidemiology
- 19. 2-Phenylphenol and Salts: Tier I Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 20. Mandipropamid: Tier I (Scoping) Review of Human Incidents and Epidemiology
- 21. Triclopyr, salts and esters: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 22. Aluminum Phosphide, Magnesium Phosphide, and Phosphine: Tier I Updated Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 23. Fenpyroximate: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 24. Myclobutanil: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 25. Mecoprop (MCPP): Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 26. Flonicamid: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 27. Carboxin and Oxycarboxin: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 28. Etoxazole: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 29. Cyproconazole: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 30. Ethoxyquin: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 31. Uniconazole-P: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 32. Fluazifop-p-butyl: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 33. Dikegulac sodium: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 34. Pinoxaden: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 35. Etridiazole: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 36. Fenamidone: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 37. Propanil: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 38. Propylene Oxide (PPO): Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 39. Pyraflufen-Ethyl: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 40. Cyazofamid: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 41. Isoxaflutole: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 42. Zoxamide: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 43. Oxyfluorfen: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 44. Fenbutatin Oxide: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 45. Thiabendazole and Salts: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 46. MCPB and Salts: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 47. Aliphatic Solvents: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 48. Pyraclostrobin: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 49. Dimethyl Disulfide (DMDS): Tier I Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 50. Methyl Bromide: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 51. Naphthalene: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 52. Flumioxazin: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 53. Clopyralid: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 54. 2,4-DP-p (dichloroprop-p): Revised Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment

Also of interest might be the <u>paraquat</u> epidemiological review and the <u>pyrethroids</u> epidemiological review links, both epi reviews of which went out very recently.

With respect to more major items we've done in past years – with links to the docket – here are some of them (with the ones in italics being the more recent ones):

Links to Tier I Epi/incident reviews available in the chemical dockets:

- ♣ Captan: https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0296-0045
- ♣ Trifluralin: https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0417-0022
- Bromoxynil: https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0896-0023

- * Imazethapyr: https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0774-0022
- ♣ Carbaryl https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0230-0035
- ♣ EPTC https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0720-0017
- Aldicarb https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0161-0024

Links to Tier II Epi/incident reviews available in the chemical dockets:

- Atrazine: https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-1156
- ♣ Diazinon: https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0091
- * Permethrin: https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0039-0084
- ♣ 2,4-D: https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0330-0084 for carcinogenic effects and https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0330-0084

for non-carcinogenic effects.

Finally, here is a link to our EPA OPP Epidemiological Framework document from December 2016 which might help you:

https://www3.epa.gov/pesticides/EPA-HQ-OPP-2008-0316-DRAFT-0075.pdf

Of course, all of the above links provide information that is public.

Item #2 from my earlier email to you below ("It would be helpful to hear more from you about the specific topics in which you are interested. I can likely talk in generalities and principles and approaches and methods. I cannot talk epidemiology associated with specific chemicals.) is something you would need to communicate to me.

Regards,

David

From: Miller, David

Sent: Tuesday, October 29, 2019 7:54 PM
To: Wibke Meyer <<u>wibke.meyer@croplife.org</u>>
Subject: RE: Epidemiology in Regulatory

Dear Wibke,

Unfortunately, as soon as 30 or 31 October would not work. The earliest would likely be late next week.

I suggest two things:

- 1) I can forward you some links to background material that might assist you to read and review ahead of time. Let me know if you'd like me to do that. It will likely include links to some recent examples of epi reviews we have completed which I think would be helpful to you in learning more about what we do.
- 2) It would be helpful to hear more from you about the specific topics in which you are interested. I can likely talk in generalities and principles and approaches and methods. I cannot talk epidemiology associated with specific chemicals.

David.

David J. Miller cart j uspus
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From: Wibke Meyer <wibke.meyer@croplife.org>

Sent: Tuesday, October 29, 2019 10:02 AM **To:** Miller, David < <u>Miller, David J@epa.gov</u> > **Subject:** Epidemiology in Regulatory

Dear David,

It was nice seeing you last week. As I mentioned briefly, I would really appreciate if I could talk to you about epidemiology. I would like to hear your views and experience with epidemiology data in regulatory, e.g. the principles of using epi data in risk assessment, suitability of studies, recommendations to the industry, etc.

Please let me know when would be a good time to call you and at which number. Would for instance 30 or 31 October in your morning work for you?

Looking forward to talking to you. Kind regards, Wibke

Dr. Wibke Meyer Manager Regulatory Affairs

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